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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/871,367	05/31/2001	Katrin Kriwet	4-30724A	1754

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THOMAS HOXIE
NOVARTIS, PATENT AND TRADEMARK DEPARTMENT
ONE HEALTH PLAZA 430/2
EAST HANOVER, NJ 07936-1080

EXAMINER
KIM, VICKIE Y

ART UNIT	PAPER NUMBER
1614	

DATE MAILED: 02/26/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/871,367	Applicant(s) KRIWET ET AL.	
	Examiner Vickie Kim	Art Unit 1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____ .

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *14-38* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *14-38* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

Election/Restrictions

1. Restriction to one of following inventions is required under 35 U.S.C. 121:

I. Claims 14, 16, 18, 20-21,23, 25, 27, 29, 31 are drawn to a are drawn to a composition for topical administration, which composition comprising (i) ascomycin, (ii) means to retain water in the outer skin layer comprising a urea, an inorganic salt, or a carboxylic acid(i.e. a cyclic carboxylic acid or salt thereof, lactic acid, glycolic acid, lactic acid sodium and/or ammonium salt, glycolic acid sodium and/or ammonium salt, lactamide, lactamidopropyl-triammonium chloride, or sodium cocoyl lactylate), and (iii) means to hinder water evaporating from the skin, clssified in class 514.

II. Claims 15, 17, 19, 22, 24, 26, 28, 30, 32 are drawn to a composition for topical administration, which comprises (i) 33-epi-chloro-33-desoxy ascomycin, (ii) means to retain water in the outer skin layer, and (iii) means to hinder water evaporating from the skin, classified in class 514.

III. Claim 33 is drawn to a method for enhancing penetration of an ascomycin using a composition of claim 14.

IV. Claim 34 is drawn to a method for enhancing penetration of an 33-epi-chloro-33-desoxy ascomycin using a composition of claim 15.

V. Claim 35 is drawn to a method for treating an inflammatory or hyperproliferation skin disease using a composition of claim 14.

VI. Claim 36 is drawn to a method for treating an inflammatory or hyperproliferation skin disease using a composition of claim 15.

VII. Claim 37 is drawn to a method for treating cutaneous manifestations of immunologically mediated diseases using a composition of claim 14.

VIII. Claim 38 is drawn to a method for treating cutaneous manifestations of immunologically mediated diseases using a composition of claim 15.

The inventions are distinct, each from the other because of the following reasons:

2. Invention of groups I-II are related as product, whereas inventions III-VIII are related to a process of using the product. The use(groups III-VIII) as claimed can be practiced with a materially different product from the product of groups I-II, and the product can be utilized in treating materially different conditions, and thus, they are considered to be patentably distinct invention.

Invention of group I is unrelated to, and considered to be patentably distinct from the other invention of group II as invention of group I are related to pharmaceutical composition containing ascomycin and a vehicle composition of claim 14 whereas invention of group II are related to a pharmaceutical composition having 33-epi-chloro-33-desoxy ascomycin as an active agent and a vehicle composition of claim 15. Because not only the active agent is different compound but also the vehicle composition of claim 14 is also different from other vehicle composition of the claim 15, invention are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different

effects (MPEP § 806.04, MPEP § 808.01). Additionally, invention of group I is independent and distinct, each from the other, as they have acquired a separate status in the art and require independent searches as evidenced by US 5385907. For instance, the patented composition(US'907) teaches the vehicle composition of claim 15 but not claim 14's. Thus, the combination of active agent in the vehicle composition would be patnetably distinct from other combination comprises different active agent in a different vehicle.

Invention of groups III-IV unrelated to, and considered to be patentably distinct from the other invention of groups V-VIII as invention of groups III-IV are related to a method for enhancing penetration whereas invention of groups V-VIII are related to a method of treatment. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). Additionally, invention of group III-IV is independent and distinct, each from the other, as they have acquired a separate status in the art and require independent searches.

Invention of groups VII-VIII unrelated to, and considered to be patentably distinct from the other invention of groups IX-X as invention of groups VII-VIII are related to a method for treating anti-inflammatory diseases whereas invention of groups IX-X are related to a method of treatment of cutaneous manifestations caused by immunological disorders. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). For instance, various

cutaneous manifestations can be characterized by non-inflammatory or non-hyperproliferative disorders(e.g. non-inflammatory acne). Invention of group V-VI is independent and distinct, each from the other, as they have acquired a separate status in the art and require independent searches.

Furthermore, applicant seems to support this restriction practice by stating the distinctiveness of applicant's present invention from the prior art of the record in the applicant's remarks and the amendment filed Sep. 09, 2002. Applicant traversed the art rejection by stating that Asakura et al's composition is distinct from applicant's present invention(as amended) because Asakura's composition contains ascomycin, fat bases(paraffin or petrolatum) and higher alkene carboxylic acids(e.g. oleic acid) as an absorption promoter whereas the present composition requires ascomycin, means to hinder water evaporating from the skin(e.g. paraffin or petrolatum), and means to retain water in the outer skin layer such as cyclic carboxylic acid(as amended) as required in the instant claim 14(see page 3, second paragraph). Applicant seems to emphasize that a carrier vehicle containing different species(higher alkene carboxylic acid vs. carboxylic acid derivatives such as cyclic or lower alkane carboxylic acids, makes the ascomycin containing composition into patnetably distinct invention. Thus, the instant restriction requirement deems to be proper and necessary to perform the accurate examination based on the patentably distinct invention as admitted by the applicant.

Election of Species

1. This application contains claims directed to the following patentably distinct species of the claimed invention:claims 39, 40, 41.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claims 14 and 15 are generic.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Conclusion

1. All the pending claims are subject to restriction/election requirement.

2. They were previously examined on the merits in the parent to this continuation application, this examiner noted that it is proper to make the restriction requirement if there is distinctness and independence any time before final action, even though the inventions were grouped together in the parent application. 37 CFR 1.142(a), see MPEP 811-811.04. Restriction requirement is necessary for the complete and accurate examination. Because the inventions are distinct for the reasons set forth in the previous office action and have acquired a separate status in the art and the search required for each group is not same, wherein a reference which anticipates the invention of Group I would not render the invention of Groups II-VIII obvious, absent ancillary art, restriction for examination purposes as indicated is proper. The search of entire groups and/or genus in the non-patent literature(especially, non-patent literature) and database search (a significant part of a thorough examination) would be burdensome, it is undue burden for examiner for the accurate

2. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Vickie Kim whose telephone number is 703-305-1675. The examiner can normally be reached on Tuesday-Friday. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Marianne Seidel can be reached on 703-308-4725. The fax phone numbers for the organization where this application or proceeding is assigned are 703-746-3165 for regular communications and 703-746-3165 for After Final communications. Any inquiry of a general nature or

relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1235.

Vickie Kim,
Patent examiner
Art nit 1614